

REMARKS

Applicants again want to thank the Examiner and her supervisor for conducting an interview with applicants' representative.

During the interview the prior art cited by the examiner in the Official Action of October 20, 2005 was discussed. Various proposals for amending the claims were also discussed during the interview. These proposals included amending claim 28 to include the subject matter of claim 29 ("wherein the colostrum fraction is prepared by a process which further includes the step of bacterial reduction utilizing centrifugation"); amending the independent claims to include the steps of reconstituting the dried colostrum retentate and administering this to the subject; including a dosage amount in the independent claims; including in claim 28 that the colostrum retentate had to be administered for at least 4 weeks; and that the colostrum was skimmed and then heat treated (e.g. pasteurized) and then subjecting the heat treated colostrum to ultrafiltration to reduce water, lactose and electrolyte levels.

Claims 28-74 are in this application. Claims 28, 40, and 62 have been amended to include the steps of reconstituting the dry colostrum and administering the reconstituted dry colostrum to the subject.

Claim 74 is new and includes the features of claims 28 and 29.

The claims were rejected under 35 USC 103(a) as allegedly being unpatentable over

AU-A-63136/94 and WO 97/16977 both in view of Clark et al. Applicant respectfully traverses this rejection and submits that the references do not set forth even a *prima facie* case of obviousness for the invention as now claimed.

As stated previously, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP Section 706.02(j).

None of the references either alone or in combination disclose a method of changing body composition and/or physical work capacity of a subject; treating a disorder of the gut or improving the psychological perception of fatigue that comprises administering to the subject a food composition containing a colostrum fraction prepared by the process set out in claims 28, 49, and 62, respectively.

WO 97/1677 discloses a method for processing colostrum and adding the processed colostrum to pasteurized or unpasteurized dairy compositions. There is no suggestion or motivation to administer reconstituted dry colostrum prepared by the process defined in claim 28 to a subject to change body composition and/or physical work capacity of a subject.

AU-A63136/94 discloses a process for the preparation of a colostrum product.

According to the first paragraph of the reference, the invention relates to a process for the preparation and storage of colostrum products. There is no disclosure in this reference nor any suggestion of a method of changing body composition and/or physical work capacity of a subject or of the benefits of independent claims 49 and 62. The reference merely describes the packaging of the processed colostrum.

Clark et al does not overcome the deficiencies of AU-A-63136/94 and WO97/16977.

On page 15, Clark states that the effectiveness of colostrum depends on its quality, and how it is processed. Clark does not disclose any specific processing conditions and just includes general comments. Clark also states that “it is very important that colostrum is standardized by taking it from large numbers of healthy cows. This insures the maximum possible amount of immune factors. Colostrum that is not standardized is, in our opinion, hardly worth taking.” The claimed invention does not require that the colostrum be obtained from a large number of cows.

Clark also states that it is their conclusion “that the most effective colostrum is that which is gently processed, but otherwise left with the balance of its immune and growth factors as nature intended.” There is no description of what Clark means by the term “gently processed.”

On page 16, Clark et al. provide a summary of standards that one should look for and

this list includes that the colostrum should be filtered and homogenized to break down long-chain proteins (immunoglobins) for better assimilation. This teaches away from applicants' invention. According to page 9, lines 3-5, of this application preferably the colostrum is treated to preserve or to enhance the levels of growth factors and other bioactive proteins, lipids or carbohydrates.

In addition on page 16, Clark states that the colostrum should be processed without added heat. In some embodiments of the invention, heat is used. See for example, claims 32, 33, 34, 35, 53, 54, 56, 66, 67 and 69.

Applicant found, surprisingly, that with correct processing an orally ingested colostrum composition could enhance exercise performance and physical work capacity; treat a disorder of the gut or improving the psychological perception of fatigue.

The claims presently on file are all directed to methods for changing body composition and/or physical work capacity, and all recite an administering step which is ingestion.

The colostrum composition of the claimed invention does have the claimed effects, as evidenced by the Examples in the specification. This was indeed an unexpected result: the manner in which the colostrum is processed and the resultant composition (which includes casein) are beneficial for providing a measurable effect on changing body composition and physical work capacity, etc.

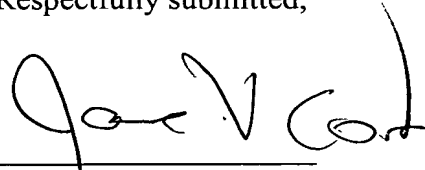
Furthermore, it is noted that Clark is a “lay” article and unlike this application does not include any scientific evidence that a colostrum product results in the advantages described above.

For example, the Clark et al. reference includes “testimonials” and the like. On page 55 of Clark et al. Bonnie; of Ogden, Utah states that she suffered from multiple sclerosis and that after taking colostrum for only a couple of months her MS symptoms have left her body. Another “testimonial” from Pete of Holladay, Utah is that colostrum caused his blood sugar levels to improve dramatically.

One skilled in the art considering Clark in combination with AU-A-63136/94 and WO 97/16977 would not reach the method claimed in this application. Accordingly, in the light of the prior art, there is no reasonable expectation of success and the references cannot be considered to set forth even a *prima facie* case of obviousness.

In view of the above, it is respectfully submitted that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Janet I. Cord", written over a horizontal line.

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